# Issuance and Reissuance of Licenses for Biological Products

## SOPP 8403

### Appendix 1

### Reissuance letter: License reissuance due to change in applicant

Name of Authorized Official
Company Name
Address

Dear (Authorized Official):

We have been advised by your letter(s) of (date(s)), that the company formerly identified as (Company Name) U.S. License No. XXXX (has merged with, or been sold to, etc.) and is now identified as (New Company Name). It is our understanding that (New Company Name) will continue to prepare (list of products) in the same manner as (Company Name), using the same equipment, manufacturing procedures and methods, and responsible personnel.

It is also our understanding that you will be the authorized official for (New Company Name). The appropriate license applications and other information required for the change in licensure have been reviewed, and found to be in compliance with the required standards.

Therefore, in accordance with the provisions in Title 21 Code of Federal Regulations Section 601.5(a), Establishment License No. XXXX issued to (Company Name), (and the Product Licenses for (list of products)), are hereby revoked, effective this date.

In addition, in accordance with the provisions of Section 351(a) of the Public Health Service Act, as amended November 21, 1997 (the Food and Drug Administration Modernization Act; Public Law 105-115), U.S. License No. YYYY is hereby issued to (new applicant name) of (address of applicant), effective this date. This license authorizes you to introduce or deliver for introduction into interstate commerce those products for which your company has demonstrated compliance with establishment and product standards.

Under this license you are authorized to introduce or deliver for introduction into interstate commerce (list of products) at (manufacturing locations).

Please submit final printed labels for each product you are authorized to prepare showing the new applicant's name and license number. Labeling revisions reflecting the new name of your establishment should be completed within 180 days of receipt of this letter.

All supplements submitted under U.S. License No. XXXX have been transferred to U.S. License No. YYYY. All future correspondence for these supplements should be submitted under the originally assigned Reference Numbers.

It is requested that you acknowledge receipt of the enclosed license. The following licenses should be forwarded to the Director, Division of Manufacturing and Product Quality (HFM-670): (list of previously issued licenses and issue dates). These licenses should be returned in order that notation of revocation may be made thereon, after which they will be returned to you for your files.

Sincerely yours,

Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Director
Office with
Product Responsibility
Center for Biologics
Evaluation and Research

(if needed)
Director
Office with
Product Responsibility
Center for Biologics
Evaluation and Research

(if needed)
Director
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Product Responsibility
Center for Biologics
Evaluation and Research